Gulf Cooperation Council

EDICT OF GOVERNMENT

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GSO 2143 (2010) (English): GENERAL REQUIREMENTS FOR RISK ASSESSMENT AND TRACEABILITY FOR GENETICALLY MODIFIED PRODUCTS (Draft Standard)

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المتطلبات العامة لتقييم المخاطر والتتبع للمنتجات المحورة وراثياً
GENERAL REQUIREMENTS FOR RISK ASSESSMENT AND TRACEABILITY FOR GENETICALLY MODIFIED PRODUCTS

Prepared by:

Gulf technical committee for standards of food and agriculture products

Foreword

Standardization Organization for G CC (GSO) is a regional Organization which consists of the National Standard s Bodies of GCC me mber States. One of GSO m ain functions is to issue Gulf Standards /Technical regulation through specialized technical committees (TCs).

GSO through the technical program of committee TC No 5 " The Gulf Technical Committee for Food and Agricultural Standards Products" has prepared this Standard . The Draft Standard has been prepared by (**KINGDOM OF SAUDI ARABIA**)

The draft Standard has been prepared based on relevant ADMO, International and National foreign Standards and references.

This standard has been approved as Gu lf (Standard / Technical Regulation) by GSO Board of Directors in its meeting No..../.... …….held on / / / H , / / G

GENERAL REQUIREMENTS FOR RISK ASSESSMENT AND TRACEABILITY FOR GENETICALLY MODIFIED PRODUCTS

1. SCOPE AND FIELD OF APPLICATION

This GSO standard is concerned with general requirements for risk assessment and traceability of GM food Processed and unprocessed agricultural products , the risk assessment and traceability should be fully considered in the safety of each new component in a GM food and c onsiders both the intended effects of the genetic modification and the unintended effects.

2. COMPLEMENTARY REFERENCES

2.1 GSO …… (General Requirements For Processed Genetically Modified Food and Feed)

2.2 GSO .....(General requirem ents for genetically modified unprocessed agricultural products

3. DEFINITIONS

3.1 Donor organism

Organism from which the transfered DNA is originally derived.

3.2 Recipient organism

Organism into which foreign DNA is introduced.

3.3 Traceability

Tracing GMOs or products produced from GMOs at all stages starting at production stage and through distribution, consumption or using in agriculture production.

3.4 Hazard

Means a biological, chemical or physical agents in or condition of, food or feed with the potential to cause an adverse health effect.

3.5 Risk

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food and feeds.

3.6 Risk Analysis

A process consisting of three com ponents: risk assessm ent, risk m anagement and risk communication.

3.6.1 RISK ASSESSMENT

A scientifically based process consisting of the following steps: hazard identification, hazard characterization, exposure assessment, and risk characterization.

3.6.1.1 Hazard identification

The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

3.6.1.2 Hazard characterization

The qualitative and /or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food or group of foods.

3.6.1.3 Exposure assessment

The qualitative and /or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

3.6.1.4 Risk characterization

The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

3.6.2 Risk management

The process of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and selecting appropriate prevention and control options if needed.

3.6.3 Risk communication:

The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers ,industry the academic community and other interested parties including the explanation of risk assessment finding and the basis of risk management decisions.

4. REQUIREMENTS

Without prejudice of what stated in GSO mentioned in items 2/1 and 2/2. The assessment of GM foods safety will be carried out on a case-by-case basis. The party of export or the exporter should provide the competent national authority of the party of import state prior to the import operation the following:

4.1 History of use

In the first part of a safety assessm ent, must looks at the hi story of use of the conventional food (the recipient or host organism).This includes identifying:

4.1.1 The edible components of the food.

4.1.2 Food products commonly containing these edible components.

4.1.3 Processing requirements.

4.1.4 The results of toxicity or allergenicity of donor organism.

4.2 Description of the genetic modification

It should provide information on the following :

4.2.1 Methods used in the genetic modification

4.2.2 Function and regulation of the new genes

4.2.3 Characterization of the new genes

4.2.4 Stability of the genetic changes

4.2.5 Effect of the new gene on human health

4.2.1 **Methods used in the genetic modification**

Must provide clear description of methods used in the genetic modification.

4.2.2 **Function and regulation of the new genes**

The applicant must provide description for the function and regulation of how the new genes function in the plant as followed:

4.2.2.1 The new genes and their products (t hat is the proteins coded for by the new genes).

4.2.2.2 The genetic m aterial that contro ls how, where and when the new genes are switched on.

4.2.2.3 The genetic material that targets any new proteins to specific parts of the cell.

4.2.3 **Characterization of the new genes**

The applicant is required to provide detailed information on the arrangement of the new genetic material in the genom e (the complete genetic make-up) of the host organism. This includes the following:

4.2.3.1 The results of standard molecular biological techniques that demonstrate how many complete or incomplete copies of the new genetic material are present.

4.2.3.2 Compares the DNA sequence of the new genetic material in the GM plant's genome with that of the original DNA.

4.2.3.3 Determining if there are any unexpected changes in the DNA sequence in the plant.

4.2.4 **Stability of the genetic changes**

The genetic changes in each GM plan t must be stable. The new genetic material is considered to have becom e a stable part of the host genom e if they

remain the same over several generations of plants produced by conventional breeding. This means that the newly introduced traits should be shown to pass from one generation to the next in a normal predictable way, following the principles of inheritance.

4.2.5 **Effect of the new gene on human health**

Must mention any effect of the new gene on human health.

4.3 Characterization of new proteins

The safety assessment must include test for nature and function of new proteins in GMO. Standard molecular and biochemical techniques can be used to verify that the size of any new protein is as expected, and to quantify how much new protein in particular tissues**.**

4.3.1 **Nature of the new protein**

The safety assessment must include test for nature and function of new proteins in GMO**,** since the presence and level of new proteins in particular components of GM varieties used as food, or in food preparation, may present safety Issues. Therefore, assesses this in the parts of GM plants that are actually eaten. It is possible that the new protein is:

4.3.1.1 Only expressed in non-edible parts of the plant.

4.3.1.2 Inactivated, denatured or removed by heat or processing (that is cooking).

4.3.1.3 Only present at very low levels in the edible part of the plant.

4.3.2 **Potential toxicity of new proteins**

This part of the assessment examines the potential toxicity of any new proteins in the GM food. The applicant must also supply data demonstrating that new proteins do not cause any detectable toxicity in animal studies. In these studies, the purified new protein is given to animals such as rats, mice and quails at high doses (100-1000 times more than a person would expect to eat in a normal portion of GM food). The animals are usually observed for a period of time (usually 90 days) after being given the protein, to determine whether there are any obvious adverse effects caused by the new protein. The animals are then sacrificed and post-mortems are used to determine any changes in pathology compared to control animals.

4.3.3 **Potential allergenicity of new proteins**

In this part of the assessment, look at whether any new protein present in the GM food is likely to cause an allergic reaction in some people. To assess the allergenic potential of new proteins, the applicant must provide information on:

4.3.3.1 Any significant allergens present in the organism that the new proteins came from.

4.3.3.2 Any significant similarity with any known allergens.

4.3.3.3 Any other physical features characteristic of allergens.

4.4 Compositional analyses

Must compare the composition of the conventional food with the GM variety, to identity differences in levels of naturally occurring nutrients, anti nutrients, toxins and allergens.

4.4.1 **Nutrient analysis**

The applicant is required to subm it the inf ormation on the analysis of the typical nutrient as followed:

4.4.1.1 Proximate composition —this refers to the approximate levels of ash, moisture, protein. fat, fiber and carbohydrate

4.4.1.2 Amino acid analysis.

4.4.1.3 Fatty acid analysis.

4.4.1.4 Carbohydrate analysis.

4.4.1.5 Vitamin and mineral analysis.

Other compounds present in particular foods m ay also be measured if they are likely to have a signif icant impact in the overall diet. For exam ple, the assessment would consider isoflavones (phytoestrogens) in soybeans.

4.4.2 **Levels of antinutrients**

Must looks at the levels of any known naturally occurring ant nutrients in the food, to check that the genetic modification has not significantly increased their levels above the natural range found in the conventional food. Processing of the foods m ust also be taken into account, because this m ay inactivate any antinutriesnts nutrients in the unprocessed food.

4.4.3 **Levels of naturally occurring toxins**

Must considers the level of any known naturally occurring toxins, to check that the genetic modification has not significantly increased levels above the natural range In the equivalent conventional food.

4.4.4 **Levels of naturally occurring allergenic proteins**

Must submit information about the levels of any known naturally occurring allergens in the food are checked to en sure that the genetic m odification has not increased the levels above the na tural range found in the equivalent conventional food.

4.5 Nutritional impact

Must provide inform ation that a GM food is nutritionally adequate and will support typical hum an growth and wellbeing. This is usually achieved by understanding the genetic modification and its consequences, and analyzing the composition of the food. If the com positional analysis indicates significant differences in a number of important nutrients or other components, or if there is concern that the bioavailability of key nutrients may be compromised by the

genetic changes to the food, then feeding studies in animals can determine whether the food is nutritionally adequate.

4.6 Other safety issues

The competent national authority may required other relevant safety issues relating to a new GM food on a case-by-case basis. In the case of nutritionally enhanced food, the nutritional impact of the changed nutrient profile on the human diet would be considered.

4.7 Domestic classification, if any, of the biosafety level of the living modified organism in the country of export.

4.8 Procedures for emergency and disposal where appropriate.

4.9 The application for GMO approval must include

4.9.1 Any risk assessment and traceability report that has been supplied to any agency for approval.

4.9.2 The results of any application that has been submitted to any other countries.

5. REQUIREMENTS OF TRACEABILITY FOR GENETICALLY MODIFIED PROCESSED AND UNPROCESSED AGRICALTRAL PRODUCTS

5.1 General Requirements

The importer must provide the competent national authority with the following information before placing foods and feeds on the market:

5.1.1 The purpose of the importing these GMO products.

5.1.2 Names and addresses of both importer and exporter

5.1.3 A manner for the safe handling, storage, transport and use.

5.1.4 A credible documentations endorsed by the embassy of imported country of origin to indicate that the product is been consumed on the country of the origin.

5.2 Special Traceability Requirements

5.2.1 **Traceability requirements for processed GMO products:**

5.2.1.1 Provide the competent national authority with all information regarding the content of the shipment whether the shipment contains or has GMO products and its special code.

5.2.1.2 Importer shall make sure the information is given written to the competent national authority.

5.2.1.3 Importer shall have in place systems and standardized procedures to allow the holding of the information specified in paragraphs 5.2.1.1 and 5.2.1.2 and the identification.

5.2.2 **Traceability requirements for un-processed agricultural GMO products:**

5.2.2.1 For unprocessed genetically modified agricultural products intended for planting or grown should provide information about the places of planting and

they should be planted in a separate area and far from the areas used for planting non-GMO.

5.2.2.2 The farmer should use only the specified area mentioned in item 5.2.2.1 for planting.

5.2.2.3 For the un-processed GMO agricultural products which used as food or animal feed, the importer provide the competent national authority with all information regarding the content of the of GMO which used from GMO and all information should be handed to final consumer through the distributors.

REFERENCES

- Cartagena Protocol on Biosafety to the Convention on Biological Diversity.
- GM foods: safety assessm ent of genetically m odified foos.2005-Food standards Australia New Zealand.
- Guideline for the conduct of food safe ty assessment of food produced using recombinant-DNA micro organisms.2003 CAC/GL.46.